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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/495,442	5 ARTER		

12M1/1125

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EXAMINER

1211

ART UNIT	PAPER NUMBER
11	

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/493,442	Applicant(s) Arter et al.
	Examiner Ralph Gitomer	Group Art Unit 1211

☒ Responsive to communication(s) filed on *Jun 22, 1995* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-17* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

It is noted the parent application to this CIP application is currently before the Board of Patent Appeals and Interferences.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-12, 14, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Arter.

Arter (Clinical Chem dated July 1993) having different inventorship than this application, entitled "Development of a Multilayered Colorimetric Assay for Serum Acetaminophen," teaches in the abstract, a multilayered colorimetric assay using aryl acyl amidase to hydrolyze acetaminophen into p-aminophenol after application of serum to the slide. P-aminophenol formed is oxidized by either tyrosinase or by ascorbic acid oxidase so that it will form a dye with tetrahydroquinoline coupler. The dye is determined and is proportional to the amount of acetaminophen present.

All the presently claimed limitations are taught by Arter for the same functions as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 13, 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Arter in view of Kawaguchi.

The teachings of Arter and their applicability to the instant invention have been discussed above.

The claims differ from Arter in that they include maleimide.

Kawaguchi (4,820,649) entitled "Method and Kit Having Layered Device for Detecting Biological Component by Interference Color" teaches in column 17 lines 22, column 18 first full paragraph, column 18 lines 32-33, maleimide groups are employed in layered detection devices and related to interferences.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ maleimides in the test strip of Arter because Kawaguchi teaches maleimides have properties desirable in test strips.

Claims 1-7, 9-12, 14, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hammond in view of either Matsumoto or deCastro and in further view of Batz.

Hammond (Analytical Biochemistry) entitled "Development of an Enzyme Based Assay for Acetaminophen" teaches on page 153 column 2, acetaminophen is enzymically hydrolyzed by aryl acylamide amidohydrolase to yield p-aminophenol and acetate. Then color reagents were studied with cyanoferrate complexes. On page 154 Table 1 teaches various color reactions and reagents.

The claims differ from Hammond in that they include a coupling agent with the color reagent and an oxidizing enzyme which couples to p-aminophenol, such as ascorbic acid oxidase, lactase and tyrosinase.

Matsumoto (4,675,290) entitled "Assaying Peptidase Enzyme Activity" teaches an assay for enzyme activity which comprises reacting an amide compound with peptidase, and treating the liberated amine with a coupler, forming a colored pigment by means of oxidative condensation in the presence of an enzyme oxidant. The reaction scheme is as follows:

(1) Amide peptidase --> amine +

(2) Coupler Enzyme oxidant --> colored product.

In column 3 compound 4 a substrate for the enzyme, an amide, is shown which upon action of the peptidase yields an amine, compound 5. Compound 5 is converted to a chromogen by oxidative condensation of the coupler, compound 3 disclosed in column 4. The coupler is described as an aromatic compound which forms a chromogen having absorption maxima at 550-750 nm. The enzyme oxidants include ascorbate oxidase, tyrosinase in column 8 line 14. In column 8 line 49 through column 9 the aniline derivative forms a chromogen with a coupler, a cyanoferric compound. In column 10 first full paragraph, various cyanoferric complexes are shown.

deCastro (4,999,288) entitled Test Composition and Method for the Determination of Anilides" teaches determination of acetaminophen with stabilized arylacylamidase which cleaves the amide bond of acetaminophen, and reagents which act as oxidizing agents and accelerate color development.

The reaction scheme is as follows:

(1) Acetaminophen arylacylamidase --> 4-hydroxyaniline (amine)+

(2) Phenol derivative (coupler) catalyst/oxidant --> colored product.

deCastro teaches periodate as the catalyst/oxidant which enables color formation to take place in one step so that all reagents can be added to the sample in one step which makes it possible to develop, dip and read test strips containing all the necessary reagents needed for testing an anilide.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oxidizing enzyme and coupling agents of Matsumoto and deCastro in the determination of Hammond because the reactions employed for the determinations are nearly identical and Matsumoto and deCastro provide motivation for employing coupling agents and oxidizing enzymes. To employ coupling agents to enhance color formation is well known in this art and is employed in the presently claimed invention for its art recognized function. Both Matsumoto and deCastro employ oxidizing agents and enzymes for the same function as presently claimed.

The present claims further differ from the above references in that they are directed to specific coupling agent compounds which encompass 1-(3-sulfopropyl)-1,2,3,4-tetrahydroquinoline.

Batz (4,845,030) entitled "Use of Aniline Derivatives As Coupling Components In Oxidative Color Formation Reactions"

teaches in column 2, structure I which encompasses the presently claimed coupling agent, 1-(3-sulfopropyl)-1,2,3,4-tetrahydroquinoline. The aniline derivatives of Batz are shown to have substantially improved color stability and a lower blank creep in oxidative coupling reactions. Substitutions with polar groups show an improved solubility and groups such as alkylsulfonic acid or sulfonic acid groups show good water solubility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific coupling agent of Batz in the determinations of Hammond, Matsumoto and deCastro because Matsumoto and deCastro teach closely related coupling agents for the same function as presently claimed. One would have a high expectation of success in substituting a known coupling agent for any of a large group of coupling agents in view of Batz because Batz teaches the presently claimed coupling agent for the same function as presently claimed.

Claims 8, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hammond in view of either Matsumoto or deCastro in further view of Batz as applied to claims 1-7, 9-12, 14, 17 above, and further in view of Kawaguchi.

The teachings of Hammond, Matsumoto and deCastro and their applicability to the instant invention have been discussed above.

The claims differ from the above references in that the element contains maleimide in the spreading layer.

Kawaguchi (4,820,649) entitled "Method and Kit Having Layered Device for Detecting Biological Component by Interference Color" teaches in column 17 lines 22, column 18 first full paragraph, column 18 lines 32-33, maleimide groups are employed in layered detection devices and related to interferences.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the maleimide of Kawaguchi in the test strips of the above references because the maleimide would have its expected function, reducing interferences.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 and all occurrences, the claim depends from claim 1 and therefore the preamble should state, "The analytical element." The preamble of claim 9 is inconsistent with that of claim 1 from which it depends. In claim 17(b) "compoound" may be intended to be "compound". In claim 17 (b) "the amount," "the concentration," and "the fluid" lack antecedent basis. Claim 17

is incomplete in that there is no determining step which would be required to correlate.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon: Deneke (4,966,855) teaches redox indicators where alkyl radicals with sulfo, phosphonic acid and carboxylic acid residues serve especially to improve solubility of the indicators.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703) 308-0204. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Ralph Gitomer
Primary Examiner
Group 1211

RALPH GITOMER
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